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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,354	02/16/2000	David K. Swanson	1928-F	6203

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HENRICKS SLAVIN AND HOLMES LLP
SUITE 200
840 APOLLO STREET
EL SEGUNDO, CA 90245

EXAMINER	
PEFFLEY, MICHAEL F	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/505,354	SWANSON ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-49 and 51-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *44-49,52-57,62 and 65-71* is/are allowed.

6)☒ Claim(s) *51, 58-61, 63 and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/23/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's amendments and comments, received March 23, 2006, have been fully considered by the examiner. In particular, applicant's arguments with respect to the 35 USC 112, first paragraph rejection of claim 56 has been deemed persuasive. Further, the cancellation of claims in copending US Serial No. 09/870,288 has obviated the double patenting rejection. It is noted that applicant has canceled claim 50, and added new claims 62-71. Also, applicant has indicated the intention to withdraw the Interference Request. The following is a complete response to the March 23, 2006 communication.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51, 58-61, 63 and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 51 recites ablating a circumferential region between an arrhythmogenic origin located along the pulmonary vein and the left atrium. There is no specific disclosure of performing such a step in the instant application. While the instant application does support the creation of a circumferential lesion, there is no specific disclosure of specifically performing the method step of isolating an arrhythmogenic

origin located along the pulmonary vein. Applicant contends that creation of the circumferential lesion would inherently isolate an origin located along the pulmonary vein (page 32 of applicant's July 11, 2000 communication) when the origin happens to be located there. While it certainly would be true, such happenstance does not explicitly provide support for the method step as recited. The method steps of claim 51 clearly acknowledge that the location of the arrhythmia origin is located in the pulmonary vein and seeks to isolate that origin. The instant application specification, on the other hand, makes no specific mention of an arrhythmia origin in the pulmonary vein. Since applicant's original specification fails to acknowledge an arrhythmogenic origin located in the pulmonary vein, applicant cannot readily support specific treatment of such an origin.

Claims 58-61 recite various alternative forms of energy used to create the circumferential lesion. Claim 58 recites the use of cryogenic energy, claim 59 recites the use of an ablative fluid, claim 60 recites the use of microwave energy and claim 61 recites the use of optical ablation energy. The examiner maintains that there is insufficient support in the specification to enable one of ordinary skill in the art to use such alternative ablation modalities with the embodiment in applicant's Figure 13. It is noted that a general statement is made in applicant's specification that these alternative energy sources may be used with the ablation element (specification page 18, lines 8-24). However, there is no discussion of how such energy forms may be employed with the embodiment of Figure 13. Each of the alternative energy sources would require a very specific delivery mechanism for delivering the energy to tissue.

For instance, the delivery of a cryogen and/or a chemical substance would require a passage through the ablation member (42(6)), and there is no disclosure of such a passage. Moreover, the delivery of a cryogen to tissue requires the use of very specific materials that can handle the extreme temperatures associated with cryogenic fluids. Applicant's specification disclose the "hoop" embodiment of Figure 13 as having a hoop formed from a resilient inert material like Nitinol, metal or silicone rubber (specification page 46, lines 33-35). There is no indication that these materials could be provided in the resilient form necessary to spring open and have the necessary qualities for delivering a cryogenic or ablative chemical. With further regard to the use of a cryogen, applicant's specification never recites the use of a cryogen. Page 18, lines 20-24 suggests that tissue could be performed by cooling. However, this is not an explicit disclosure of the use of a cryogen. While cryogen is one typical means by which tissue is cooled for ablation, there are other means to cool tissue for ablation, such as the use of thermoelectric cooling electrodes.

Similarly, the use of microwave energy and laser energy presents other delivery issues which are not enabled and/or supported by applicant's specification. A microwave energy emitter would typically require a coaxial antenna and would radiate energy in all directions (unless provided with a blocking mechanism to radiate in a particular direction). A laser energy source would require a delivery means such as an optical fiber. There is nothing in applicant's specification that would enable one of ordinary skill in the art to make the resilient member of Figure 13 with the necessary structural components to delivery microwave and/or laser energy.

With regard to claim 63, applicant now recites a tissue ablation device "having a shape corresponding to the orifice". There is insufficient support in the originally filed specification to support such a limitation. First, it is not entirely clear what is meant by "corresponding to the orifice". It is the examiner's position that such a limitation imparts more than the ability to encircle the orifice, as supported in the original specification. Rather, "corresponding to the orifice" implies a specific size relationship that would correspond the size of the ablation device to any of the given orifices. There is no specific disclosure that the ablation element "corresponds" to an orifice. Only that the ablation device may encircle any of the SVC, IVC or pulmonary veins.

Allowable Subject Matter

Claims 44-49, 52-57, 62 and 65-71 are allowed.

Response to Arguments

Applicant's arguments filed March 23, 2006 have been fully considered but they are not persuasive.

Applicant contends that claim 51 does not call for a step of "locating an arrhythmia origin in the pulmonary vein". Rather, the claim merely indicates that "a left atrial arrhythmia originates at least in part from an arrhythmogenic origin located along the pulmonary vein" and that one of ordinary skill in the art would understand that the claim simply acknowledges the presence of a naturally occurring condition. The examiner maintains that the specification, as originally filed, failed to indicate that the device may be used to treat such a naturally occurring condition and therefore cannot

claim a method that specifically treats the condition. The creation of lesions may also treat other naturally occurring conditions, such as misfires from the Bundle of His, but applicant cannot claim to treat these conditions merely because they may be present. Applicant has in no way indicated in the originally filed specification that arrhythmogenic origins located in the pulmonary vein were known, identified or treated, and positively treating such a condition as recited in claim 51 is deemed to be new subject matter.

Concerning claims 58-61, the examiner notes that these claims are method claims and that to be enabling, the specification need only describe the method steps in enough detail to allow one of skill in the art to practice the method. The examiner agrees and maintains that there is insufficient description to allow one of ordinary skill in the art to practice the method as set forth in claims 58-61. As addressed previously, there is no disclosure of how the instrument of Figure 13 may be modified to treat tissue with the alternative modalities. Also, there is no indication that there are suitable prior art devices having these alternative modalities that could perform the method steps as set forth in claims 58-61. The examiner sees no suggestion in the prior art or in applicant's specification to adequately support the modification of the RF electrode device of Figure 13 into a device that could deliver cryogenic, ablative fluid, microwave or optical ablation energy in the given procedure.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Peffley
Primary Examiner
Art Unit 3739

mp
May 5, 2006